REMARKS

Claims 1-5, 7-25, 27-40 and 46 are pending. Claim 51 is new. All pending claims except claims 4, 21 and 22 are rejected. Claims 4, 21 and 22 are objected to, but the basis for the object is not set out in the office action. Applicants infer that the basis for the objection is that claims 4, 21 and 22 depend from a rejected claim, and those claim's would be allowable if re-written in independent form. Confirmation of that understanding is respectfully requested.

All pending claims are rejected under 35 U.S.C. §102(e) as anticipated by Canham US 2005/0048859, filed December 20, 2002. The problem with the rejection is that the examiner picks and chooses different paragraphs from the reference, but the references fails to teach the use of the cited features **in combination** as required by the claims. In fact, it seems clear that the reference does not contemplate the proposed combination of features.

Canham is a general disclosure relating to a broad range of uses for silicon containing medical fibers and fabrics [paragraph 0001]. The Background section of Canham indicates just how broad the disclosure is. After discussion the art of fibers and fabrics as practiced by the ancient Egyptians to close wounds with [paragraphs 0002-0004], the reference says,

> [0005] These products may have a variety of medical applications, depending upon their precise nature and form. For example, fibres and fabrics may have general surgical applications, for examples as **sutures, threads or meshes**. In the cardiovascular fields, they may be incorporated for example in **artificial heart valves**. Orthopaedic **prostheses such as tendons and ligaments** utilise products in the form of fibres and fabrics and they may also have percutaneous/cutaneous applications such as in **shunts and artificial skin**. [Emphasis is added].

> [0006] The particular materials currently used in medical textiles include modified natural polymers, synthetic nonabsorbable polymers and synthetic absorbable polymers.

> [0007] However, most commercial polymer textile fibres have various additives (such as dyes, antistatic agents, delustrants, photostabilisers) which may reduce their biocompatibility and thus limit the options for using these in medical applications. Although some may be biodegradable, it is difficult to ensure that fibres do not lose their mechanical strength at too early a stage in the tissue replacement process.

In short, Canham's disclosure is broadly related to new medical fibres and textiles containing silicon [paragraph 0008].

The Applicants' claims on the other hand are directed to very specific medical applications: stents, stent-grafts, grafts, medical balloons and catheters [claim 1].

It is not true that Canham teaches the use each and every feature it discloses in stents or the other recited medical devices.

Claim 1, for example, requires that the fiber be ceramic with a metalloid (e.g. silicon). The Examiner cites paragraph 10 of Canham,

> [0010] As used herein, the term "silicon" refers to elemental silicon material **which is a semiconductor**. For the avoidance of doubt, it does not include silicon-containing chemical compounds such as silica, silicates or silicones, **although it may include composites of semiconducting silicon combined with medical-grade polymer, ceramic or metal phases**. It may also include **doped semiconducting silicon** where concentrations up to the atomic percent level of elements like boron or phosphorus are incorporated into the silicon lattice to raise electrical conductivity. Porous silicon may be referred to as "pSi", crystalline silicon as "c-Si" and amorphous silicon as "a-Si".

So it is of course true that Canham discloses the general possibility of semiconducting silicon fiber that includes a ceramic phase. And it is true that, at paragraph 90, Canham discloses stents as one of many possible uses for the silicon-containing fabrics:

> A stent is a mesh-like collar designed to serve as a temporary or permanent internal scaffold to maintain or increase the lumen of a vessel. Essential stent features include radial and torsional flexibility, biocompatibility, visibility by X-ray and reliable expandability. It is an example of a widely used implant that is currently engineered from malleable but non-biodegradable materials such as metals. A silicon or silicon containing fabric as described above, may form the basis of these stents. Particular preferred fabrics would comprise biodegradable forms and partially porous forms for eluting drugs locally. These forms would be possible using fully or partially porous silicon fibres as described above, in the production of the stents.

The problem with the rejection is that Canham nowhere propose the use of the disclosed semiconducting material **in a stent, stent graft, balloon, or catheter.** The Examiner must consider what Canham says about the applications where such semiconducting properties are useful. It describes various forms of silicon, including microparticles which are chemically

bonded to cotton, linen or synthetic fabrics [paragraph 21], silicon "incorporated into the fiber [paragraph 0029], deposition [0034], silicon microwires [0037], etc. Among all of these varied uses for the fibers and fabrics, it discloses that some, such as "implants, prosthesis and the like where controlled levels of electric current may be applied to stimulate incorporation into the body" [paragraph 0012]. It is those applications where the art suggests the use of semiconductors:

> [0085] Such fibres and fabrics are particularly useful in medical applications since the semiconducting nature allows for good distribution of electrical charge, where these are used in therapy. A particular form of such a fabric is a silk based fabric which comprises silk warp threads and low resistivity silicon containing weft threads.
>
> [0086] Thus in a further aspect the invention provides a method for enhancing tissue growth, which method comprises applying to a patient in need thereof, a semiconducting fabric comprising silicon, and passing controlled levels of electrical current through said fabric.
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> [0089] The electrical conductivity of the textile is also of benefit in orthopaedic applications where osteogenesis is controlled by application of distributed electrical charge. Invasive bone growth stimulators that utilise a wire mesh cathode are currently used in spinal fusion.
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> [0091] A further possible application for the fabrics described above is in flexible electrodes for neuro-interfacing. The macroporosity of the fabric enables tissue in-growth. In addition, the fibres used are preferable at least partially mesoporous, which means that they offer lower impedance. In order to ensure the very high electrical conductivity and stability which is important in such devices, in this case, it may be preferable to use fibres comprising a non-porous heavily doped silicon core, with a porous silicon layer that has been electroplated with an ultrathin conformal coating of a metal such as platinum or iridium.

Canham discloses other applications which do not necessarily involve semiconducting fabrics, and it is in that context that Canham mentions stents (see paragraph 90 quoted above):

> [0087] Fibres and fabrics as described above have a variety of medical applications. For example, fabrics which have large pores (>100 micron) for cellular

infiltration can be used as scaffolds for tissue engineering. The use of the different fabrication techniques listed above provides for exceptional flexibility of 2D topography.

[0088] They may also be of use in orthopaedic prostheses where the mesoporosity of the fibres provides bioactivity whilst the macroporosity of the textile pattern directs and allows bone in-growth.

In short, it is improper to read the document as a whole and conclude (as the Examiner has) that the cited disclosure about semiconducting material applies to every possible application for the fibers Canham discloses, and in particular to the unrelated disclosure about stents. Nor is it proper to conclude that the art provides any reason other than semiconducting to use a combination of two separate metalloids.

So the rejection of claim 1 must be withdrawn.

The flaw in the rejection is even more pronounced when applied to claim 2, which requires the presence of a second metalloid, e.g. boron, in the ceramic fiber used in a stent, stent graft, medical balloon or catheter. New claim 51further specifies that the fiber is used in a stent. The Examiner cites paragraphs 0010 and 0042 of Canham in support of his conclusion that Canham anticipates claim 2. As we have seen the relevant disclosure in paragraph 0010 of Canham broadly defines silicon, as including

> doped semiconducting silicon where concentrations up to the atomic percent level of elements like boron or phosphorus are incorporated into the silicon lattice to raise electrical conductivity.

It is particularly remote to infer a disclosure of the use of such boron-doped silicon in a stent, and Canham provides no rationale leading to such a use. So the rejection of claims 2 and 51must also be withdrawn for reasons that go beyond the analysis of claim1.

In addition, those skilled in the art would not conclude that the claimed ceramic which requires two separate metalloids reads on a ceramic that includes boron-doped silicon. Boron-doped silicon is effectively a single metalloid composition. As the art points out, the doping is intended to "raise electrical conductivity", and the boron is **incorporated in to the silicon** at a

level of up to 1 atomic percent % -- i.e., 1 mole of boron: 99 moles of silicon, as a maximum boron level.

> [0012] Furthermore, such fibres or fabrics may have semiconducting properties, which may be particularly useful in the context of certain applications, for example, in implants, protheses [sic, prostheses] and the like, where controlled levels of electric current may be applied to stimulate incorporation into the body.

The single phase semiconducting material that Canham discloses does not meet the claim requirement of two separate metalloid entities.

> "[The term 'silicon'] may also include doped semiconducting silicon where concentrations **up to the atomic percent level** of elements like boron or phosphorus are incorporated into the silicon lattice to raise electrical conductivity. Porous silicon may be referred to as "pSi", crystalline silicon as "c-Si" and amorphous silicon as "a-Si"." [Emphasis is added].

In sum, the disclosure in Canham does not anticipate claim 2 or claim 51because:

1. The claims specify the two metalloids as two separate entities in the material, not as a single material with semiconducting properties. and
2. Even if claim 2 does read on boron-doped semiconducting material, there is absolutely no disclosure that such material should be used in a stent or other device specified in claim 2.

For these reasons the art does not disclose a **stent having two metalloids** and anticipate claims 2 and 51and the rejection must be withdrawn.

Similarly, claim 5 requires an additional non-metallic element. The Examiner cites paragraph 10 quoted above which generally discloses that the silicone fiber may include a polymer, but there is no disclosure whatsoever indicating that such a feature is to be used in a stent or other device listed in claim 1. When it comes to picking among the various types of fabrics disclosed, Canham is simply an invitation to experiment to establish the properties of each of the wide range of possibilities of combinations and permutations that Canham discloses.

Under those circumstances the Examiner may not assume that all such permutations and combinations are to be used in stents.

For at least the reasons provided above, Applicant believes that claims 1-5, 7-25, 27-40, and 46 are in condition for allowance, which action is requested.

Please apply any charges to deposit account 06-1050.

Respectfully submitted,

Date: 11/2/2006

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